



Total Mortality Rates Across

Multiple Databases: Benchmarking results from a Distributed Data Network - The SAFEGUARD Project

Authors: John D. Seeger¹, Silvana Romio^{2,4}, Cristina Varas-Lorenzo³, Lorenza Scotti⁴, Andrea Arfè⁴, Antonella Zambon⁴, Miguel Gil⁵, Gema Requena⁵, Irene Bezemer⁶, Giorgia De Berardis⁷, Corinne de Vries⁸, Ingrid Leal⁹, Gwen Masclee⁹, Gianluca Trifirò⁹, Peter Rijnbeek², Cormac Sammon⁸, Niklas Schmedt¹⁰, Mark Smits¹¹, Giovanni Corrao⁴, Miriam Sturkenboom²

Institutions:¹ The Brigham and Women's Hospital, Harvard Medical School, Boston, United States; ² Erasmus University Medical Center, Rotterdam, Netherlands; ³ RTI Health Solutions, Barcelona, Spain; ⁴ University Milano-Bicocca, Milan, Italy; ⁵ Spanish Agency for Drugs and Medical Devices, Madrid, Spain; ⁶ PHARMO Institute, Utrecht, Netherlands; ⁷ Consorzio Mario Negri Sud, Santa Maria Imbaro, Italy; ⁸ University of Bath, Bath, United Kingdom; ⁹ Fondazione Scientifica SIMG-ONLUS, Firenze, Italy; ¹⁰ Leibniz-Institute for Prevention Research and Epidemiology - BIPS GmbH, Bremen, Germany; ¹¹ VU University Medical Center, Amsterdam, Netherlands

Background

In order to assess the association between diabetes drug exposure and select disease outcomes including total mortality, a network of European data sources has been established. This network, named the Safety Evaluation of Adverse Reaction in Diabetes (SAFEGUARD), has applied common definitions to identify a range of patient outcomes of interest to the study of medications for treating type 2 diabetes.

Objectives

To estimate mortality incidence rates across the data sources involved in the SAFEGUARD project.

Methods

Parent Project

- SAFEGUARD is a multinational research project funded by the European Commission to study the safety of blood glucose-lowering medications, except insulin, in patients with type 2 diabetes mellitus.
- SAFEGUARD includes mechanistic, pharmacovigilance, database-based observational studies, and systematic reviews on the pancreatic and cardiovascular safety of these blood glucose-lowering medications.

Mortality Benchmarking

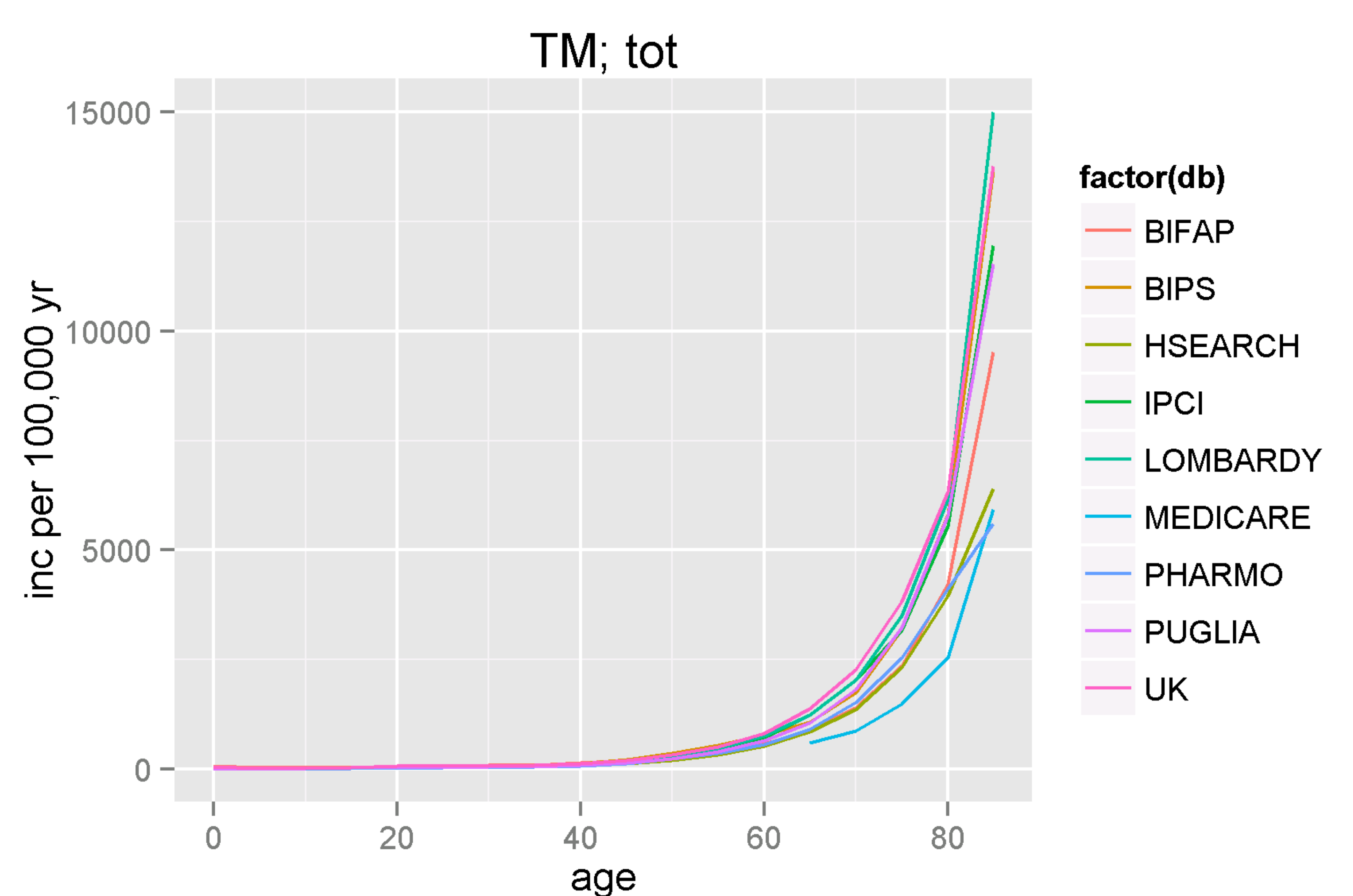
Mortality data from eight data sources representing the Netherlands (IPCI, PHARMO), Italy (SISR Lombardy, SISR Puglia), UK (CPRD), Spain (BIFAP), Germany (BIPS/GePaRD), and the US (Medicare) were combined. Data sources cover time between 1999 and 2012 depending on data availability. Data were extracted locally using consistent definitions that were tailored to meet unique features of each data source, and were processed using standardized software (JERBOA) running at each site. The processed output from each site represented a tabulation of overall mortality within pre-defined age and sex strata.

Results

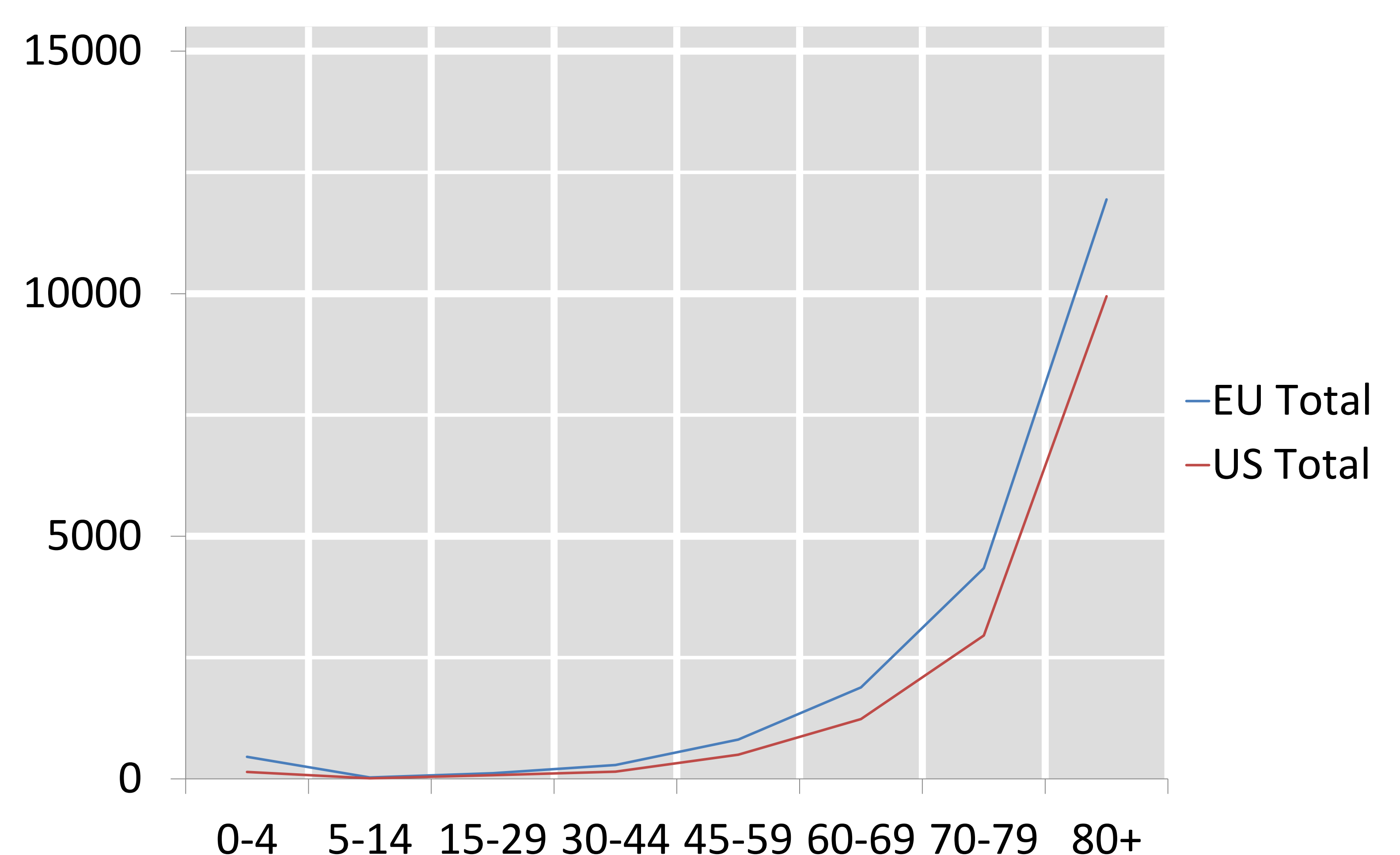
The average mortality rates (per 100,000 person-years) combining the data sources were approximately 400 (ages 45-54), 1,000 (ages 55-64), 2,000 (ages 65-74), and 6,000 (ages 75-84). Total mortality incidence varied by as much as two-fold across data sources within age and sex strata. The age and sex-specific all-cause mortality from each source was consistent with external mortality references from the EU and US.

Results

Mortality Incidence by Data Source



External reference: Europe – WHO Mortality; US – CDC Mortality



Conclusions

The SAFEGUARD project will evaluate mortality across different data sources. Descriptive analysis of seven of the included databases provides a mechanism by which distributed data sources can arrive at harmonized mortality incidence.

Author Contact Information

John D. Seeger: jdseeger@partners.org

Conflict of Interest Statement

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• J Seeger is a consultant to Optum Insight and WHISCON.

C. Varas-Lorenzo as employee of RTI Health Solutions participates in project advisory boards funded by pharmaceutical companies